

**REMARKS/ARGUMENTS**

This Amendment is filed in response to the Office action that was mailed on December 31, 2007. Claims 1-63 and 67 are pending in this Application. Claim 55 has been withdrawn from consideration and Claim 9 has been amended. The amendments do not introduce new matter as they are fully supported by the claims, specification, and drawings as originally filed or are inherent characteristics thereof. Applicants respectfully request reconsideration and allowance of all claims in view of the following remarks.

**Claim Rejections – 35 U.S.C. § 112**

Claims 24, 25 and 31 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. It is indicated in the Office action that Claim 24 recites the limitation “a resilient material included in the roller and having properties susceptible to tearing in response to an instrument inserted into the working channel.” It is also indicated in the Office action that nowhere in the Specification does Applicant disclose the resilient material is susceptible to tearing and that the Examiner understood that the Applicant intended to recite the resilient material is not susceptible to tearing and will be considered as such for examination purposes. Applicants respectfully traverse this rejection.

Applicants respectfully submit that the material of which the roller of Claim 24 is made, although having a high tear strength, is susceptible to tearing, such as when the roller is in contact with a sharp instrument. It is the fact that the material is formed into a moveable roller that tearing of the material is inhibited. Support for this proposition is

found in the Specification. More particularly, the Specification, at page 13, lines 2-3, recites, "This particular material is a gel material 80 which has properties including a low durometer hardness and a high tear strength." Additionally, the Specification, at page 13, lines 24-29, recites, "Forming this gel material 80 into a roller, such as the rollers 38 and 41, adds the further advantage of protecting the gel material against any tendency to tear or propagate due to insertion of a sharp instrument. With the roller configuration, a sharp point engaging the outer surface of the roller 38, for example, will cause the roller 38 or 41 to rotate on its axis and ultimately disengage the sharp instrument point without tearing the gel material 80." Based on the Specification, the gel is susceptible to tearing, but the roller configuration protects the gel against any tendency to tear.

Based on the foregoing, Applicants respectfully submit that support for the resilient material being susceptible to tearing is provided in the Specification, as originally filed. Applicants respectfully request that this rejection be reconsidered and removed.

Claims 1, 15, 24, 47 and 48 are rejected under 35 U.S.C. § 112, second paragraph, because the recitation of the limitation "zero seal in the absence of the instrument, and an instrument seal in the presence of the instrument" is unclear, thereby rendering the scope of the claims unascertainable. It is indicated in the Office action that the Examiner interprets the limitation as a gas tight seal in the absence of the instrument and a gas or fluid tight seal in the presence of the instrument. Claims 2-5, 7-9, 12, 16-23, 25, 31 and 54 are also rejected as dependent from the rejected

claims. Similarly, Claim 18 is rejected because the recitation of the limitation "zero seal" is unclear, thereby rendering the scope of the claim unascertainable. Here, the Examiner interprets the limitation as a gas tight seal or fluid tight seal. Applicants respectfully traverse this rejection.

Applicants hereby acknowledge that the Examiner's interpretation of a zero-seal is one appropriate interpretation thereof. While the present invention has been described in certain specific aspects, many additional modifications, variations and interpretations would be apparent to those of ordinary skill in the art. It is therefore to be understood that the present invention may be practiced otherwise than specifically described in the Application, including various changes in the size, shape and materials, without departing from the scope and spirit of the present invention. Thus, embodiments of the present invention provided in the Application should be considered in all respects as illustrative and not restrictive. Those of ordinary skill in the art will recognize that other appropriate interpretations of a zero-seal may exist and such interpretations are not hereby disclaimed. Based on the foregoing, Applicants respectfully request that these rejections be reconsidered and removed.

Claim 9 was rejected under 35 U.S.C. § 112, second paragraph, because the recitation of the limitation "the instrument seal having a diameter with a lower limit of about zero millimeters" is unclear, thereby rendering the scope of the claim unascertainable. It is also indicated in the Office action that the limitation "zero millimeters" indicates that the instrument does not exist or the portion that is inserted into the trocar does not exist. Applicants respectfully traverse this rejection.

Claim 9 has been amended to recite the instrument seal having a diameter with an upper limit in a range between about six millimeters and twelve millimeters, while removing the lower limitation. Applicants respectfully submit that support for this amendment is found in the Specification, Claims and Drawings as originally filed, or are inherent characteristics therein. Applicants respectfully request that this rejection be reconsidered and removed.

### **Claim Rejections - 35 U.S.C. § 102**

Claims 1, 2, 4, 5, 7, 8, 9, 12, 15, 17, 18, 21, 22, 47 and 48 are rejected under 35 U.S.C. § 102 (b) as being anticipated by U.S. Patent No. 5,360,417 to Gravener et al. (Gravener '417). To be anticipating, a prior art reference must disclose each and every limitation of the claimed invention, the prior art must be enabling, and the prior art reference must describe the claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the field of the invention. *Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339 (Fed. Cir. 2000).

It is indicated in the Office action that Gravener '417 discloses (see FIGS. 22 and 23) a trocar adapted to provide access for a surgical instrument through a body wall and into a body cavity (see Summary of the Invention), comprising: a cannula (64) having a proximal end and a distal end; a seal housing, which contains valve (10) assembly, communicating with the cannula to define a working channel; a seal assembly includes valve (10) and rollers (96) disposed within the seal housing; two pinching members or rollers (96), wherein each having an axle supported by the seal housing; and the rollers having properties for forming a gas tight seal or fluid tight seal

with or without the presence of an instrument (see col. 8, lines 10-40). Applicants respectfully traverse this rejection.

Independent Claim 1 of the present Application recites the at least one roller having properties for forming a zero seal in the absence of the instrument and an instrument seal in the presence of the instrument. Similarly, Independent Claim 15 of the present Application recites the roller being sized and configured to form a zero seal in the absence of the instrument and an instrument seal in the presence of the instrument. Additionally, Independent Claim 47 of the present Application recites a roller valve having properties for forming a zero seal across the working channel in the absence of the instrument, and an instrument seal across the working channel in the presence of the instrument. Applicants respectfully submit that Gravener `417 fails to teach the roller having properties for forming an instrument seal in the presence of an instrument.

FIGURES 22 and 23 of Gravener `417 depict pinching rollers (96) spring-pressed in an opposing relationship into contact with the middle portion (28) of the valve assembly (10), thereby pinching or biasing the middle portion (28) of the valve assembly (10) in a closed position substantially preventing gases from entering or exiting (see Gravener `417 column 8, lines 10-25). In other words, FIGS. 22 and 23 of Gravener `417 depict the pinching rollers (46) forming a zero seal when no instrument is present.

The embodiment of the valve assembly of FIG. 23 of Gravener `417 is similar to the embodiment of the valve assembly of FIG. 22 (Gravener `417, col. 8, lines 40-42), which in turn is similar to the embodiment of FIG. 21 (Gravener `417, col. 8, lines 10-

12). In describing FIG. 21, Gravener `417 (col. 7, line 61 through col. 8, line 3) recites that "tight contact between the instrument (44) and the inner wall (34) [of the valve assembly] has sealed the inner body cavity from the outside atmosphere. This seal is provided by the resilient property of the stretched elastomeric material at middle portion (28) surrounding the aperture (14). Manipulation of the instrument (44) in any direction will not affect the seal, since the elastomeric material defining the aperture (14) will conform to the movements of the instrument and assume a shape necessary to maintain contact." (Emphasis added.) Gravener also describes the aperture (14) typically being dimensioned less than or equal to the diameter of any instrument intended for entry into the proximal end of the body (12) (col. 5, lines 9-11), and the proximal opening (22) being of such a diameter to sealingly engage instrument (44) during insertion and withdrawal (col. 5, lines 29-31).

Based on this description from Gravener `417, the middle portion (28) of the aperture (14) is dimensioned smaller than or equal to any instrument intended for entry therethrough, and thus an instrument seal is provided as the material in that region stretches around the instrument. In this manner, there is no need for the pinching members (96) in providing an instrument seal in the embodiments depicted in FIGS. 22 and 23 of Gravener `417.

In relation to FIG. 22, Gravener `417 recites the middle portion (28) of valve assembly (10) provides longitudinal and radial pressure in conjunction with pinching members (96) to the instrument, thus providing and maintaining a substantial gas tight seal (i.e.; an instrument seal) (col. 8, lines 35-39). However, Gravener `417 fails to indicate, in any way, how or why the pincher members (96) contribute to providing the

instrument seal. If, as described in earlier embodiments, the middle portion (28) of aperture (14) is dimensioned smaller than the instruments inserted therethrough, then it is the middle portion (28) of the aperture (14) that provides the instrument seal as it stretches over the instrument.

If, for argument sake, the middle portion (28) of FIGS. 22 and 23 of Gravener '417 was larger than an instrument inserted therethrough and required assistance to form an instrument seal, Applicants respectfully submit that the pincher rollers (96) would not be adequate to provide the instrument seal. As described in Gravener '417 (col. 8, lines 10-39), the pinching members (96) are generally cylindrical and have a shaft (97) extending longitudinally through each of the pinching members. The shaft (97) extends into a groove (98) in a plate (100) connected to the inner surface of the lower housing half section (62). The shaft (97) rides freely in the groove (98). Springs (106) positioned in each of the grooves (98) bias the shafts (97), and thus the pinching members (96). Upon insertion of an instrument, the pincher members (96) are moved in response to actuation of levers (90) and (92), and shafts (97) respond by moving in their corresponding grooves (98).

In this manner, the pincher members (96) would move away from each other when an instrument is inserted into the valve assembly (10). If the middle portion (28) of the aperture (14) is larger than the instrument inserted therethrough, then when the levers (90) and (92) are released and the springs (106) bias the pincher members (96) toward the middle portion (28) of the aperture (14), the middle portion (28) would collapse by the pressure from the pincher members and form a point contact on each side of the instrument (44) and openings between the middle portion (28) and the

instrument away from the point contacts. Therefore, the pincher members (96), are not adequate to form an instrument seal. In the embodiment of FIGS. 22 and 23 of Gravener '417, it is the middle portion (28) of the aperture (14) that forms the instrument seal.

Based on the foregoing, Applicants respectfully submit that Gravener '417 fails to disclose each and every element of independent Claims 1, 15 and 47. Hence, Gravener '417 cannot anticipate Claims 1, 15 and 47, and Claims 1, 15 and 47 are allowable over Gravener '417. As Claims 2, 4, 5, 7, 8 and 12 depend from independent Claim 1, Claims 17, 18, 21 and 22 depend from Claim 15, and Claim 48 depends from Claim 47, Applicants respectfully submit that they are also allowable as depending from allowable base claims. Applicants respectfully request that these rejections be reconsidered and removed.

#### **Claim rejections – 35 U.S.C. § 103**

Claim 3 and 23 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Gravener '417. It is indicated in the Office action that referring to Claim 3, FIG. 22 of Gravener '417 discloses the pinching member has a pivotal relationship with the axle (88), wherein axle (88) is fixed with respect to the housing. Applicants respectfully traverse this rejection.

Applicants respectfully submit that, contradictory to what is presented in the Office action, there is no item (88) in FIG. 22, and the axles on which the pinching members (96) of FIG. 22 pivot, or rotate, are actually axles (97). Axles (97) of FIG. 22 extend into respective grooves (98) and ride freely therein (Gravener '417, col. 8, lines



15-22). Hence, the axles (97) do not have a fixed relationship with the seal housing, as they float therein. Based on the foregoing, Applicants respectfully submit that a prima facie case of obviousness is not established and Claim 3 is allowable over Gravener '417. Applicants also respectfully submit that Claim 3 is allowable as depending from allowable Claim 1 and respectfully request that this rejection be reconsidered and removed.

Referring to Claim 23, it is indicated in the Office action that Gravener '417 discloses the invention substantially as claimed except for the housing and the roller being formed of translucent material. It is also indicated in the Office action that it is old and well known in the art that trocar housings and cannulas are formed of translucent or transparent materials. Applicants respectfully traverse this rejection.

Claim 23 depends from independent Claim 15. As indicated above, Applicants respectfully submit that Claim 15 is allowable over Gravener '417. Applicants further respectfully submit that Claim 23 is allowable as depending from an allowable independent claim. Based on the foregoing, Applicants respectfully request that this rejection be reconsidered and removed.

Claims 16, 19, 20, 24, 25, 31 and 54 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Gravener '417 in view of U.S. Patent No. 6,238,373 to de la Torre et al. (de la Torre '373). It is indicated in the Office action that Gravener '417 discloses the invention substantially as claimed except for the roller including a gel material. It is further indicated in the Office action that de la Torre '373 discloses such

a material for his device (col. 10, line 52 to col. 11, line 15, and FIG. 16-16a).

Applicants respectfully traverse this rejection.

Claims 16, 19 and 20 depend from independent Claim 15. As indicated above, Applicants respectfully submit that Claim 15 is allowable over Gravener `417, and further submit that de la Torre `373 does nothing to correct this deficiency. Hence, Applicants respectfully submit that Claims 16, 19 and 20 are allowable as depending from an allowable independent claim. Based on the foregoing, Applicants respectfully request that this rejection be reconsidered and removed.

Independent Claim 24 recites a roller disposed within a seal housing, and a resilient material included in the roller. The resilient material provides the roller with properties for forming a zero seal in the absence of the instrument and an instrument seal in the presence of the instrument. As indicated above, Gravener `417 fails to provide a roller with properties for forming an instrument seal, and Applicants respectfully submit that de la Torre `373 does nothing to correct this deficiency. De la Torre `373 teaches a gel positioned within a skin (46) or a membrane, and having a slit therein for insertion of an instrument. Although de la Torre `373 teaches the use of a gel material, neither Gravener `417 nor de la Torre `373, either together or alone, discloses any teaching, suggestion or motivation to combine the pincher member (96) of Gravener `417 with a gel material to create a roller having properties for forming an instrument seal.

Based on the foregoing, Applicants respectfully submit that a prima facie case of obviousness is not established and Claim 24 is allowable over Gravener `417 in view of de la Torre `373. As Claims 25 and 31 depend from independent Claim 24, Applicants

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respectfully submit that they too are allowable as depending from an allowable independent claim. Reconsideration and removal of this rejection is respectfully requested.

Claim 54 depends from independent Claim 47. As indicated above, Applicants respectfully submit that Claim 47 is allowable over Gravener '417, and further submit that de la Torre '373 does nothing to correct this deficiency. Hence, Applicants respectfully submit that Claim 47 is allowable as depending from an allowable independent claim. Based on the foregoing, Applicants respectfully request that this rejection be reconsidered and removed.


### **Conclusion**

Applicants respectfully request that a timely Notice of Allowance be issued in this case. If the Examiner believes that a telephone conference with Applicant's attorney might expedite prosecution of the Application, the Examiner is invited to call at the telephone number indicated below.

Sincerely

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